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Registration Decision RD2013-04

# N-Alkyl (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate and Ethyl Alcohol

*(publié aussi en français)*

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# Registration Decision for N-Alkyl (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate and Ethyl Alcohol

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Onyxide 3300 and SD Alcohol, and the end-use product Lysol Brand III Disinfectant Spray, as sanitizers for use on fabric (soft porous surface). Onyxide 3300 and SD Alcohol contain the technical grade active ingredients n-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium saccharinate and ethyl alcohol, respectively, while the end-use product Lysol Brand III Disinfectant Spray contains both n-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium saccharinate and ethyl alcohol.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-21, *N-Alkyl (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate and Ethyl Alcohol*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for n-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium saccharinate and ethyl alcohol and summarizes the Agency's decision. The PMRA received no comments on PRD2012-21. This decision is consistent with the proposed registration decision stated in PRD2012-21.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-21, *N-Alkyl (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate and Ethyl Alcohol* that contains a detailed evaluation of the information submitted in support of this registration.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

## What is Compound N-Alkyl (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate and Ethyl Alcohol?

N-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium saccharinate is a quaternary ammonium compound. These compounds are cationic surfactants that disrupt membranes. No products are currently registered with this active ingredient. Ethyl alcohol is known to kill microorganisms by denaturing their proteins and dissolving their lipids. Ethyl alcohol is effective against a wide range of microorganisms.

## Health Considerations

### Can Approved Uses of N-Alkyl (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate and Ethyl Alcohol Affect Human Health?

**Lysol Brand III Disinfectant Spray, containing Onyxide 3300 and SD Alcohol, is unlikely to affect your health when used according to label directions.**

Potential exposure to n-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium saccharinate and ethyl alcohol may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

Onyxide 3300 was of moderate acute toxicity via the oral route of exposure. An acute inhalation study conducted with another structurally related chemical, alkyl dimethyl benzyl ammonium chloride (ADBAC), indicated that this chemical was moderately acutely toxic via the inhalation route, and it is expected that Onyxide 3300 would exhibit the same acute inhalation toxicity profile. Onyxide 3300 was of low acute toxicity via the dermal route of exposure. It was extremely irritating to the eyes and moderately irritating to the skin. It did not cause an allergic

skin reaction. As a result of the acute toxicity findings, the following signal words and hazard statements are required on the label: "DANGER – CORROSIVE TO EYES. SKIN IRRITANT", "POISON".

When assessing the toxicity of Onyxide 3300, it was considered appropriate to use repeat-dose animal studies performed with another structurally related chemical, ADBAC. The health effects following exposure to ADBAC are considered to be representative of Onyxide 3300.

ADBAC did not cause cancer in animals and did not damage genetic material. There was no indication that ADBAC caused damage to the nervous system. ADBAC did not cause birth defects in animals and there were no effects on the ability to reproduce. Following repeated dosing in laboratory animals there was no specific target organ toxicity. Generalized toxicity was observed in rats, mice and dogs as decreases in body weight, body weight gain, and food consumption, which in some cases were accompanied by clinical signs of toxicity. Mortality occurred at higher doses and likely reflected the corrosive nature of the test substance.

When ADBAC was given to pregnant or nursing animals, no effects on the developing fetus or juvenile animal were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to ADBAC than the adult animal.

The risk assessment protects against the effects of Onyxide 3300 by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

The toxicity of ethyl alcohol is extensively documented. Long-term repeated ingestion of ethyl alcohol may result in the development of progressive liver injury or exacerbate liver injury produced from other causes. Repeated ingestion of ethyl alcohol by pregnant mothers has been shown to adversely affect the central nervous system of the fetus, producing a collection of effects which together constitute the fetal alcohol syndrome. These effects include mental and physical retardation, disturbances of learning, motor and language deficiencies, behavioural disorders, and small head size.

Considering the history of wide use of ethyl alcohol in consumer and pharmaceutical products and the frequent human exposures to products containing ethyl alcohol, no health concerns are anticipated from the exposure to ethyl alcohol in the Lysol Brand III Disinfectant Spray.

In laboratory animals, the end-use product Lysol Brand III Disinfectant Spray was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and not irritating to the skin. Lysol Brand III disinfectant Spray did not cause an allergic skin reaction.

**Risks in Residential and Other Non-Occupational Environments**

**Estimated risk for non-occupational exposure is not of concern provided that directions for use specified on the label are observed.**

Residential exposure to individuals applying Lysol Brand III Disinfectant Spray, containing n-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium saccharinate and ethyl alcohol, on fabric (soft porous surface) is not expected to result in unacceptable risk when it is used according to label directions.

A postapplication risk assessment conducted for individuals contacting porous fabric items treated with the Lysol Brand III Disinfectant Spray indicated that risk to adults and children is not of concern when the product is used according to label directions.

## Environmental Considerations

Based on the use pattern of the end-use product, an environmental assessment was not required.

## Value Considerations

**What Is the Value of Lysol Brand III Disinfectant Spray?**

**Lysol Brand III Disinfectant Spray is used to kill bacteria in fabric (soft porous surfaces) not typically washed.**

Lysol Brand III Disinfectant Spray contains two active ingredients n-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium saccharinate and ethyl alcohol. Together they treat fabrics against bacteria proliferation. The value of this product is that it can be used on fabrics that are difficult to wash such as draperies, fabrics covering car seats, rugs, *etc*.

## Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label Lysol Brand III Disinfectant Spray to address the potential risks identified in this assessment are as follows.

**Key Risk-Reduction Measures**

**Human Health**

No residential risk is expected from using Lysol Brand III Disinfectant Spray on fabric (soft porous surface) according to label directions. Since this is a domestic class product, no personal protective equipment is recommended on the label.

**Environment**

Not applicable

## Other Information

The relevant test data on which the decision is based [as referenced in PRD2012-21, *N-Alkyl (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate and Ethyl Alcoho*] are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.